# Connecting Patients With Specialty Products

## Part 2: The future of specialty drug distribution

Previously, this series described distribution channels through which specialty drugs move to patients. This installment discusses changes and challenges that lie ahead, especially at the dispensing end.

BY JACK MCCAIN

By 2018, 7 of the 10 top-selling drugs in the United States are expected to be specialty pharmaceuticals, compared with 3 in 10 today. Costs associated with this shift will be tempered by plummeting sales of popular brand-name drugs owing to the emergence of generic substitutes. In fact, aggregate U.S. spending for the top 10 drugs in 2018 could be lower (in constant dollars) than it is for the top 10 sellers today.

With that, we'll soon need a new definition of *blockbuster,* says Adam J. Fein, PhD, president of Pembroke Consulting, in Philadelphia.

The change may forever alter the way prescription drugs are distributed and dispensed. Today, distribution channels rely heavily on the dominance of brand-name drug manufacturers, though specialty pharmaceuticals have begun to force an evolution of that system. Specialty drugs are shaking up retail pharmacy; their complexity challenges specialty pharmacies (SPs) to sharpen support services; and their cost gives new importance to the pharmacy benefit manager (PBM).

### Getting drugs to patients

The basic way distribution channels affect payers' costs is that the fees collected from manufacturers by wholesalers, specialty distributors, and large national SPs — the three main players on this stage — get wrapped into the price of the drugs. "There's nothing a health plan can do about that," says Ron Krawczyk, managing partner of Chesterfield, Mo.-based Blue Fin Group, a life-sciences management and technology consultancy. Wholesalers and specialty distributors frequently ship products to physicians, small SPs, and retail pharmacies for dispensing, placing the flow of products through these channels largely beyond the sphere of payer influence.

Health plans have more opportunity to manage distribution channels to their advantage by working with the large SPs. "One of the services SPs advertise is saving money for payers," Krawczyk notes, "so health plans will partner with an SP and negotiate the services it will provide. In turn, the SP will negotiate with manufacturers for price and services." Such services may include compliance programs and disease-specific patient education.

In a 2011 survey of medical and pharmacy directors at 102 health plans representing 122 million lives, 81 percent of the plans said they required members to use the services of at least one SP in their specialty pharmacy networks (EMD Serono 2012). About half the commercial plans mandated use of an SP for about half a dozen therapeutic categories. Medicare Advantage prescription drug plans mandated SP use in these categories to a lesser extent (Figure 1, page 14); plans without mandates allowed members to obtain self-administered specialty drugs through a retail or mail-order pharmacy or on their own through an SP.

**The move by legacy retail pharmacies** into specialty pharmaceuticals reflects the future of pharmacy, says Adam J. Fein, PhD, president of Pembroke Consulting, in Philadelphia.

Fein sees good times ahead for independent SPs. He points to 10 such enterprises on *Inc.*'s 2011 list of the fastest-growing private U.S. companies — all but one has been started since 1996. Fein calculates the average 3-year growth rate for this group at 208 percent. The oldest of this group, Diplomat Specialty Pharmacy, founded in 1975, has grown large enough to earn a slice of the SP pie (Figure 2, page 15).

Community retail pharmacists

are anxiously watching as the influx of inexpensive generics trim their revenues. "Within 5 years, generics will account for 85 to 90 percent of retail dispensing," says Fein. "Pharmacies will sell them like over-the-counter drugs at lower profits. If you want to stay involved in pharmacy, you will need to get involved in specialty pharmaceuticals."

But, says Fein, most retail pharmacies aren't well suited to deal with issues associated with specialty drugs, such as special handling — a "must have" service in the eyes of most payers. A more successful strategy, he says, would be to focus on disease areas, such as hepatitis C or HIV, where fewer handling concerns translate to fewer manufacturer restrictions on distribution channels — thus giving pharmacies easier access to specialty products. Small retailers taking this approach tend to focus on a single disease area and market their expertise to physicians in that area.

That opens tremendous potential for specialty pharmacy. Krawczyk says that at a recent large SP conference, attendees were bullish about the future of SPs, particularly because of retailers' interest. "Retail pharmacies are trying to recreate themselves as SPs because of their loss in brands," says Krawczyk. Chain pharmacies, in particular, are chasing the action — as CVS has done so well since merging with Caremark and as Walgreens is now doing (see page 16).

If retailers are interested in adding SP capabilities, wholesalers and specialty distributors are interested in helping them for one simple reason — they want to hold on to their customer base. "It's in the wholesalers' interest to find a solution for retailers who want to become SPs," says Krawczyk. "Otherwise, their business will decline as well."

**Looking ahead,** says Ron Krawczyk, at Blue Fin Group, there's plenty of room in the distribution models for hubs to provide services such as assistance with adherence or coordination of care related to innovative new drugs.

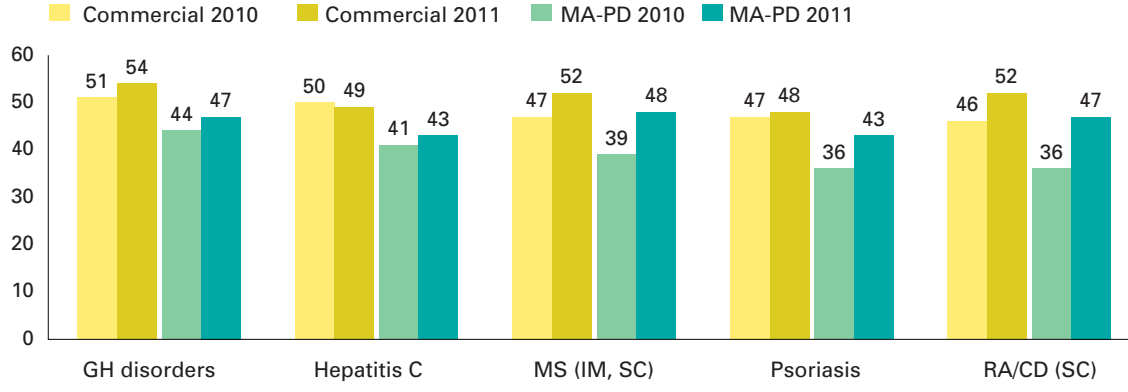
## Bye-bye to buy-and-bill?

With oral oncolytics, the channel matters a great deal to both payers and physicians. As oral oncolytics replace infused products, oncologists see a growth opportunity, says Fein, because so many oral oncolytics are in the pipeline. For their part, payers see an opportunity to curtail costs by distributing oral oncolytics through SPs rather than having physicians purchase and administer them. Oncologists argue that care is best when they provide the drugs and see patients when a drug must be administered, but payers want greater control over utilization. Fein says the evidence supports both viewpoints. "Many market participants advocate for different positions, depending on where they sit."

Although some medical and pharmacy directors would like to see buy-and-bill fade into oblivion, Krawczyk thinks rumors of its demise are greatly exaggerated. "If buy-and-bill is dead, why are McKesson Specialty Care Solutions, Oncology Supply, Besse Medical, and ASD [the

**FIGURE 1**

**Commercial and Medicare Advantage plans mandating use of specialty pharmacies, by therapy category**




CD=Crohn's disease, GH=growth hormone, IM=intramuscular, MA-PD=Medicare Advantage Prescription Drug Plan, MS=multiple sclerosis, RA=rheumatoid arthritis, SC=subcutaneous.

Source: EMD Serono 2012

four major specialty distributors] so bullish on it? AmerisourceBergen's specialty businesses support buy-and-bill, and they invest in infrastructure to support their customers in what may be greater than $18 billion in sales to physician offices. Buy-and-bill is not going away."

And while payers might try to diminish buy-and-bill by encouraging use of patient-administered drugs over office-administered medications, Krawczyk says there aren't yet enough self-administered alternatives for that approach to succeed. Moreover, he says, payers that encourage patients to self-administer may encounter stiff resistance from physicians who have legitimate concerns about the safety of home-based administration. For many patients, Krawczyk says, the physician's office is, in fact, the ideal site of care.

Buy-and-bill conducted through manufacturer-stipulated channels provides one safeguard for health plans and members: protection from counterfeit medications. The high prices of specialty drugs could spur the growth of electronic methods of tracking a product to guarantee that the product is legitimate. If physicians acquire office-administered products through authorized distribution channels, counterfeit drugs should never be a problem.

## Role of the PBM

Outside the supply chain, consolidation among wholesalers and PBMs continues. The chief importance of PBMs to payers is that the largest PBMs own the largest SPs, and the big PBMs — by virtue of their size — are positioned to negotiate the most favorable prices with the manufacturers of specialty products.

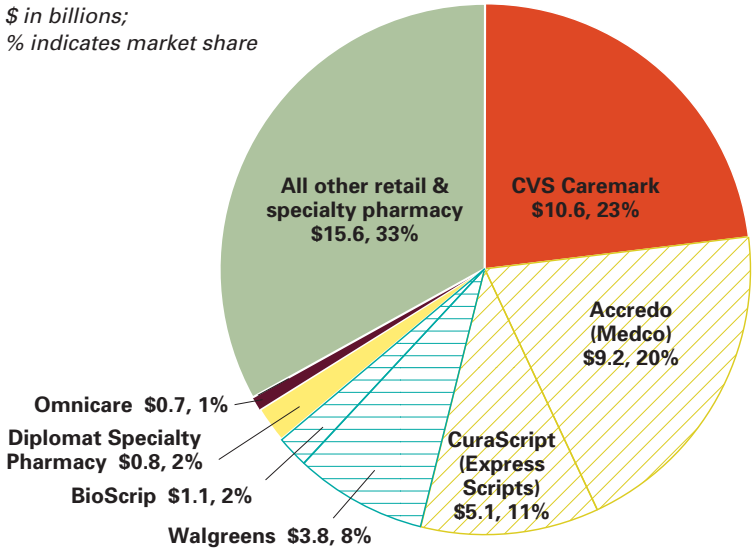
One of the major services PBMs provide is to construct P&T committees, whose members recommend drugs for placement on a plan's formulary. The PBM's size matters during negotiations with the drug manufacturers. Assuming a drug is efficacious and safe, if the manufacturer provides competitive pricing and rebates, then the PBM often will recommend that it receive preferred formulary status. PBMs share rebates with sponsors as a flat, guaranteed per-script rebate or as a percentage of rebates with or without a guaranteed minimum.

Overall, PBMs share about 80 percent of rebates with plan sponsors, Fein says, but sponsors may contract for up to 100 percent of rebates if they have negotiating clout with the PBM. Though rebates apply to specialty products and traditional drugs alike, specialty drugs generally do not come with substantial rebates, he says — the exceptions being categories with many therapeutically comparable alternatives, such as growth hormone.

Distribution channels don't figure directly into formulary placement, but they could indirectly affect formulary placement in an important way, says Krawczyk. If a payer's SP is unable to fill a prescription because of the drug's flow through restricted channels, the payer would be able to provide access to the product through another SP in the manufacturer's distribution network. Lack of easy access (and higher costs) could lead the plan's SP partner to recommend placing this drug on a higher tier, such as a fourth tier, or on a specialty tier.

**FIGURE 2**
**Estimated revenues from specialty drugs, by specialty pharmacy, 2011**

*$ in billions;*
*% indicates market share*




Striping indicates corporate mergers finalized in 2012.

In 2011, retail and specialty pharmacies dispensed $47 billion in specialty pharmaceuticals, or 17% of total pharmacy revenues. The top 4 companies accounted for 62% of revenues in this sector. Walgreens acquired some of BioScrip's assets in May (see page 16), and is now the third largest company in this sector. The combined market share of Express Scripts and Medco is likely to decline in 2012 and 2013 owing to the loss of various contracts: Walgreens withdrew from Express Scripts' retail pharmacy network; Medco lost UnitedHealth's commercial business and the contract for the Federal Employee Program, which went to Caremark.

Source: Pembroke Consulting 2012

## 'If you're in pharmacy today, you're in specialty pharmaceuticals'

Walgreens, the nation's largest drugstore chain, is an example of a company that made its name in retail pharmacy, starting with its founding in 1901, and has been branching out to capture a substantial portion of the specialty pharmaceuticals business.

Ray Tancredi, RPh, MBA, now in his fourth year as Walgreens' vice president for specialty pharmacy development, says Walgreens embraced specialty products for the same reason the rest of the industry did: A substantial percentage of drugs in the pipeline are specialty pharmaceuticals. "If you're in pharmacy today, you're in specialty pharmaceuticals," he says.

Or, at least, you should be, adds Ron Krawczyk, managing partner of Blue Fin Group, a life sciences consultancy. "It is good to be Walgreens."

Walgreens began expanding into specialty pharmacy services in 2005. Its largest acquisition was the 2007 $850 million purchase of Option Care, which gave Walgreens a network of 100 specialty pharmacies and home-infusion businesses in 34 states, plus specialty pharmacy contracts with more than 400 MCOs. The company's diverse specialty pharmaceutical distribution channels include workplace health centers and outpatient pharmacies within health systems. And last May, Walgreens acquired some BioScrip assets, including centralized specialty and mail-service businesses and 30 community specialty pharmacies in 16 states and the District of Columbia.

That positions Walgreens to get specialty drugs to patients via every channel available. The company says its multichannel approach sets it apart from competitors that tend to rely on central fill.[1]

Initially, specialty pharmaceuticals meant injectables, but now the industry is leaning toward oral drugs, Tancredi says. That trend has facilitated Walgreens' entry into the specialty arena because it reduces the need for special storage facilities.

To solidify its position in specialty products, Tancredi says, Walgreens has developed the "specialty-at-retail" approach by which the company's Specialty Pharmacy Resource Center enables pharmacists at most of its retail outlets to handle specialty drugs. The resource center coordinates prior authorization activities and handles other issues, thus lightening the workload of the local pharmacist. Limited-access products often must be acquired via central fill, but from the patient's perspective, says Tancredi, the process is seamless.

[1]*Central fill* is a pharmacy that fills prescriptions from a central location and then delivers them directly to the consumer's home. Mail pharmacies are central fill.

### A bright future

Looking to the future, Krawczyk sees abundant opportunities arising from the anticipated onslaught of new specialty pharmaceuticals. He says there's plenty of room in the distribution models for hubs to provide basic services — attracting patients to therapy, initiating therapy, and keeping patients on therapy. Despite the notion that cancer patients are highly motivated to stay on therapy, poor adherence is a major problem — rates have been documented as low as 16 percent (Ruddy 2009).

Beyond adherence support, Krawczyk envisions the development of important new services as innovative specialty products come to market. Should any of the anti-amyloid agents in development gain U.S. Food and Drug Administration approval, for instance, hubs could offer services to coordinate the care of Alzheimer's patients prior to therapy initiation, and dedicated neurology infusion suites could emerge for intravenous products.

Specialty pharmaceuticals are rapidly gaining market share, and continued growth of the specialty sector is expected to the extent that it will dominate U.S. drug sales.

Manufacturers exert ultimate control over the design of distribution channels, but health plans and employers have opportunities to seek contracts with PBMs that work to the benefit of members and employees who use specialty drugs. In the future, patients are likely to gain convenience in acquiring self-administered specialty pharmaceuticals along with a broad array of services from PBMs and pharmacists.

### References

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